WORKING GROUP GUIDANCE MATERIAL RECOMMENDATIONS APPROVAL HOLDER QUALITY SYSTEM REQUIREMENTS

1. PURPOSE. This document provides information on the quality system requirements for all Production Approval Holders (Production Certificate, Parts Manufacturer Approval and Technical Standard Order Authorization).

2. DEFINITIONS AND ABBREVIATIONS. As used herein, the following definitions and abbreviations apply:

a. Product. An aircraft, aircraft engine, propeller, or any appliance that has been designated by the administrator as type certificated.

b. Part. Any item not identified as a product including but not limited to: an article for which the FAA has issued a Technical Standard Order; Accessory; appliance that has not been designated by the Administrator as type certificated; airborne software and firmware; and components and parts of a product or part.

c. Supplier. Any person who furnishes services to a holder of a production approval which affects a type certificated product, or who supplies parts for installation on a type certificated product, including parts which were not designed or manufactured by the type certificate holder.

d. Regional Office. The Branch of the Federal Aviation Administration region having jurisdiction over the geographical area in which the manufacturer is located.

e. District Office. The FAA District Office (CMO / MIDO) responsible for evaluation and inspection of the manufacturer's facilities.

f. PC. Production Certificate (Ref. FAR 21, Subpart G).

g. PMA. Parts Manufacturer Approval.

h. TSOA. Technical Standard Order Authorization.

h. PAH. Production Approval Holder – the holder of a PC, PMA or TSOA.

3. DISCUSSION. This circular covers only those sections of FAR 21, Subpart G, where further discussion, information, and examples would be helpful. The heading of each of the following main paragraphs refers to the applicable section of Subpart G.

4. FAR 21.139 – PRIVILEGES.

a. While a PAH is proceeding with a design approval of a new product or part of the same type that is on its Production Limitation Record, it may produce those products or parts under its approved quality system, so that the PAH may be ready to release them for service as soon as the design of the new product or part is approved by the FAA. The quantity of products or parts produced in this manner should be limited and reasonable in relationship to planned requirements. The PAH must have a system to positively identify and disposition products and parts produced in this manner that do not conform to the design approved by the FAA.[1]

b. If a production certificate holder produces products and related parts prior to design approval per paragraph 5.a., the production certificate holder may also ship those products and parts prior to design approval if there is a positive recall system in case the design is not approved. An FAA airworthiness approval may be issued for such products and parts as long as it is clear on the airworthiness approval that the parts were released in this manner.[2]

5. FAR 21.141 – RESPONSIBILITY OF THE PRODUCTION APPROVAL HOLDER.

a. The PAH shall immediately notify the FAA in writing of any change to the location of a manufacturing facility or any change to the quality system that could affect the inspection, conformity, or airworthiness of the product or part. Notification in writing would include electronic communication.

b. The PAH shall determine that each completed product or part conforms to the approved design and is in condition for safe operation prior to its release. The holder of a production certificate has a basic responsibility for controlling the manufacture of completed products and spare articles in conformity with his FAA-approved quality control data and design requirements.

(1) Although this responsibility never changes, he may be relieved of some of the burden of inspection and testing duties when he:

(a) Uses other type certificated product or products manufactured under another person's production certificate, or which bear an FAA Airworthiness Approval Tag, FAA Form 8130-3.

(b) Uses articles produced under an FAA TSO authorization.

(c) Installs used parts that conform to the type design.

(d) Uses parts fabricated under an FAA Parts Manufacturer Approval.

(e) Delegates specific inspection and testing duties to suppliers.

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[1] The inclusion of this item in the NPRM should be verified by the FAA.

[2] This paragraph need not be included if AC 21-32 remains active.

(2) The production approval holder remains responsible for controlling the design, physical configuration, and operating condition of the parts or products furnished by a supplier. However, the holder of a production approval may be relieved of some of the burden of inspection and testing when these functions are delegated to a supplier. All changes made by a supplier, to the design or the physical product or part, must be submitted to the holder of the production approval for evaluation and approval as applicable under FAR 21, Subpart D. Thus, the holder of a production approval is responsible for obtaining FAA approval of major materials review actions or other design changes including those made to supplier furnished articles which were not designed or manufactured by him and would also result in a change to his design data or to his products or parts.

c. In those instances where the PAH is not the design approval holder, the PAH is required to report to the design approval holder the following items necessary for analysis and possible reporting under § 21.3. This will ensure that the persons responsible for the original design and who hold the design approval are kept informed of these items, so they may determine if there is any impact on the airworthiness of the product.

(1) All deviations from the quality system which could have an impact on the airworthiness of the product or part.

(2) All undocumented nonconforming products or parts which could have left the quality system. These parts are typically referred to as "escapes", and do not include parts which were dispositioned as acceptable by the Material Review Board.

d. The PAH shall maintain a complete and current technical data file consisting of all the approved data and manufacturing processes for each product or part manufactured under the production approval. The file shall be retained for the period of manufacture of the part or product or as agreed upon with the Administrator.

e. The PAH shall maintain complete quality records for 2 years for manufactured products or parts and 10 years for critical components as defined under 14 CFR 45.14.

f. The PAH shall obtain an airworthiness approval, in accordance with Order 8130.21, for each shipment of completed products and/or parts. This requirement does not apply to shipments within the PAH's quality system. This provides a standardized "birth certificate" for each part or batch of parts.

g. The PAH shall mark products in accordance with 14 CFR Part 45. This provides uniform marking requirements for all parts sold as spares to assure that all individuals can readily determine whether a part is eligible for installation on a product for which a type certificate has been issued.

h. The PAH shall allow the Administrator to make inspections, tests, and investigations at its facilities or any supplier facilities necessary to determine compliance with applicable regulations. Following the issuance of the production approval, the FAA will maintain periodic surveillance of the production facilities and quality control system, through

management by a Principal Aviation Safety Inspector and by the use of periodic inspection team audits. If the FAA determines that any part of the data or system which was originally approved does not fully meet the applicable requirements, the FAA will request changes to the quality control system or data as may be required.

NOTE: The FAA considers any evidence of inspection approval placed on inspection records, test reports, or physical articles as documentation that the article, process, or manufacturing operation has been accepted by the holder of a production approval.

(i) The PAH shall have accessible the approval and ratings in the manufacturing facility. The holder of a production approval may make copies of the production approval for use in associate facilities.

6. FAR 21.143 – AMENDMENT, TRANSFERABILITY, AND DURATION OF A PRODUCTION APPROVAL. A PAH may request an amendment to the approval through its District Office. This may include a request to move the location of the PAH's manufacturing facility.

a. Application to amend a production approval is made in the same form and manner as the original issue, except that only changes to the existing quality control data need be submitted, when production of the new product involves changes in the quality control system. If no changes in the quality control data are required, or if the applicant is adding a product / part of the same type as currently covered under the existing production approval, the situation should be documented by letter to the district office.

b. Since a production approval may be amended for several different purposes, the following paragraphs provide examples as to methods applicable in differing circumstances:

(1) The holder of a production approval may make application to move the manufacturing facility. Upon evaluation and approval of the application of the quality control data in the new manufacturing facility, as applicable, the FAA will modify the production approval showing the new address.

(2) When production of completed products as well as spare articles has ceased, the holder of a production approval should request deletion of the applicable products/parts from his production limitation record by a letter to the regional office. A revised production limitation record will be issued, and the superseded production limitation record would be cancelled.

(3) If the holder of a production certificate ceases to manufacture complete products, but continues to manufacture spare articles, his production limitation record does not require an amendment.

7. FAR 21.145 – QUALITY SYSTEM. A total quality control system meeting the requirements of FAR 21.145 would provide control over all phases of manufacture, including control over the manufacture of all supplier-furnished articles. The control exercised by the manufacturer over articles furnished to the manufacturer by a supplier that holds his own FAA approval for the article may be limited to the approval of the supplier's material review systems, design changes, and to the manufacturer's usual incoming quality control procedures employed after articles are received from an outside source. The FAA has reviewed the aviation industry's quality standard AS9100 published by SAE, and has made a determination that it meets the requirements of this section. This should facilitate the FAA approval of an applicant's system that is in accordance with AS9100.

8. FAR 21.147 – QUALITY SYSTEM DOCUMENTATION

a. The data required to be submitted for approval under this regulation should be submitted to the district office at the same time the application for a production approval is submitted.

b. In general, the quality system requirements are self-explanatory, and the following paragraphs provide an example of acceptable compliance:

(1) The manufacturer's organizational structure required by FAR 21.149 would ensure that any decisions with regard to workmanship, quality, conformity, safety, materials review, and corrective action are not influenced by other considerations. This can be achieved by having the quality control organization report directly to top management.

(2) An effective quality control system utilizes well-qualified personnel in sufficient number to ensure that all articles, processes, procedures, and the completed products are inspected for conformity to data, specifications, and procedures specified in the approved design.

(3) The quality control data would be arranged in manual form (either in hardcopy or electronic version), with a suitable index, and should cover each portion of the quality system requirements.

(4) When references to other company documents or data are utilized, the manual would briefly summarize the procedure, method, or system which is referenced. Any such referenced material becomes part of the data approved by the FAA.

(5) In providing the documentation required by FAR 21.147, the inclusion of, or reference to, supplementary data such as the following is considered helpful in showing acceptable compliance:

(a) Copies of all inspection and acceptance forms and checklists for articles and completed products, together with a brief outline of instructions for their use.

(b) Imprints of the various inspection and process stamps, and their meaning.

(c) A typical schedule of inspection and calibration intervals for production jigs and fixtures, precision inspection tools, testing equipment, including gauges and recording equipment used in controlling processes.

(d) A listing of manufacturing processes which are relied upon to assure quality, conformity, and safety of the completed product.

c. An acceptable means of compliance with FAR 21.155 would be to provide in the quality control data a description of the system used to evaluate, monitor, and control all suppliers to whom the holder of a production approval has delegated inspection duties for controlling conformity and quality. Such a description would include an up-to-date listing, either in the manual or in a referenced company document, of all such suppliers by name, address, general nomenclature of articles or services, and any other pertinent information, such as:

(1) Reference to the manufacturer's quality control manual by title and date.

(2) Delegation of Material Review Board (MRB) authority.

(3) Name and title of the manufacturer's or supplier's quality representative(s) who will make available purchase orders, drawings, and other applicable data.

9. FAR 21.149 through FAR 21.165 – QUALITY SYSTEM FUNCTIONS.

a. A totally integrated quality control system would include the following major functions listed in FAR 21.149 through 21.165. A cross-reference of those functions with the applicable AS9100 functions is given. The FAA has found the AS9100 document (issued 1999-11) to be a comprehensive quality standard containing the basic quality control elements required by the current Code of Federal Regulations (CFR) Title 14, Part 21. The organizational system that meets the elements of AS9100, if effectively employed, should also meet the FAA's expectations for a manufacturing quality control system and are shown here for reference purposes

CFR Title 14, Part 21	**AS 9100 (issued 1999-11)**
§ 21.149 Management Responsibility	§ 4.1 Management Responsibility
§ 21.151 Design and Data Control	§ 4.4 Design Control § 4.5 Document and Data Control
§ 21.153 Document Control	§ 4.5 Document and Data Control
§ 21.155 Supplier Control	§ 4.6 Purchasing
§ 21.156 Process Control	§ 4.9 Process Control
§ 21.157 Inspection and Testing	§ 4.10 Inspection and Testing
§ 21.158 Inspection, Measuring, and Test Equipment Control	§ 4.11 Control of Inspection, Measuring, and Test Equipment

CFR Title 14, Part 21	AS 9100 (issued 1999-11)
§ 21.159 Inspection and Test Status	§ 4.12 Inspection and Test Status
§ 21.160 Nonconforming Products, Parts, Materials, and Services Control	§ 4.13 Control of Nonconforming Product
§ 21.161 Corrective and Preventive Action	§4.14 Corrective and Preventive Action
§ 21.162 Handling, Storage, Packaging, Preservation, and Delivery	§ 4.15 Handling, Storage, Packaging, Preservation, and Delivery
§ 21.163 Control of Quality Records	§ 4.16 Control of Quality Records
§ 21.164 Internal Quality Audits	§ 4.17 Internal Quality Audits
§ 21.165 Final Release of Product or Part	§ 4.12 Inspection and Test Status

b. When establishing the Quality System, the following must be considered:

(1) Articles obtained from foreign suppliers are under the same degree of control that is exercised over domestic suppliers. In general, an undue burden may exist whenever the production approval holder performs, or he has suppliers perform, any of his regulated functions outside the United States. Under such circumstances, the evaluation and approval of design changes and the evaluation, approval and subsequent surveillance of manufacturers, including the supervision of designees performing outside the United States may create a burden on the FAA in administering the FARs. In accordance with FARs 21.43 and 21.137, the determination of whether or not an undue burden exists must be made by the FAA in each case. FAA surveillance of materials, parts, and appliances is not considered to be an undue burden when:

(a) The manufacturer completely inspects such articles for conformity and condition upon receipt in the United States; or

(b) An agreement is negotiated between FAA, the foreign civil aviation authorities and the U.S./foreign manufacturers where-by the foreign civil aviation authority agrees to perform inspections and surveillance on behalf of the FAA, and certifies to the FAA that each article conforms to the FAA-approved design and is in a condition for safe operation; or

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(c) The foreign civil aviation authority at the country of manufacture certifies that the article meets U.S. requirements in accordance with FAR 21.502.

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(2) Ensure the submittal of all material review actions, which result in a major change in the design data, to the FAA and obtain FAA engineering approval prior to final acceptance or delivery of affected products or parts. The materials review system is a method acceptable to the Administration for the approval of minor changes in design in lieu of submitting to the Administrator any substantiating or descriptive data (Ref. FAR 21.95) including manufacturing errors.

(3) There must be a record of all inspections and tests required to be conducted during manufacture of the products or parts. Those significant records attesting to the conformity and safety of the completed product or part must be retained for a period of at least

two years for most parts and ten years for life limited and life assessed parts, and other parts serialized as required by Section 45.14.

(4) There must be a system to control the packing, preservation, and condition of parts that incorporates procedures which ensure that:

(a) Parts conform to applicable design data and have not exceeded their shelf-life limits.

(b) Prior to shipment of parts, all required modifications are accomplished in accordance with applicable design changes.

(c) Parts are lubricated, preserved, and packed in a manner to preclude corrosion or damage in shipment, especially internal damage not readily detectable by inspection for condition upon receipt.

(5) Service Difficulties. A totally integrated quality control system would include the means of recording, investigating cause, and assuring corrective action on all known or reported failures, malfunctions, and defects, including procedures, as applicable to each particular manufacturer, to ensure that:

(a) Service problems are investigated and prompt corrective action is taken on all affected products as appropriate.

(b) Users of the product are informed of service difficulties and resultant FAA-approved changes to the type design in accordance with FAR 21.99 requirements.

(c) Feedback on service problems is received from users of the products to the extent practicable.

(d) Requirements of FAR 21.3 relative to the reporting of certain malfunctions and defects are satisfied.

APPENDIX 1 – Additional Production Certificate Information

Application

An application for a production certificate is made on FAA Form 8110-12, (OMB-04-R0078) Application for Type Certificate, Production Approval, or Supplemental Type Certificate, which is submitted to the regional office.

Evaluation and Issuance

Upon receipt of a properly executed FAA Form 8110-12, and following a district office preliminary survey and evaluation of the applicant's quality control data and system, the FAA will convene a production certification board (consisting of one or more persons) at the applicant's facilities to make the final determination for issuance of a production certificate. The applicant will be formally advised as to the extent of his assistance needed in the production certification board activities, and of the findings and recommendations of the district office and the production board. Where the facilities, equipment, data, procedures, and personnel of the applicant are found to meet the applicable requirements of FAR 21, Subpart G, a Production Certificate will be issued.

Production System Limitations

If the production approval board finds that the applicant's facilities, equipment, data, procedures, and personnel do not meet all sections of FAR 21, Subpart G, the FAA may issue a production approval with specific limitations and / or special requirements to compensate for the lack of compliance to those sections. These limitations / special requirements may include the specific testing requirements applied to products produced under "TC Only" under the previous FAR 21 Subpart F regulations. These consist of:

(1) Tests: aircraft

(a) An approved production flight test procedure and flight check-off form, and in accordance with that form, a flight test each aircraft produced.

(b) Each production flight test procedure must include the following:

1 An operational check of the trim, controllability, or other flight characteristics to establish that the production aircraft has the same range and degree of control as the prototype aircraft.

2 An operational check of each part or system operated by the crew while in flight to establish that, during flight, instrument readings are within normal range.

3 A determination that all instruments are properly marked, and that all placards and required flight manuals are installed after flight test.

4 A check of the operational characteristics of the aircraft on the ground.

5 A check on any other items peculiar to the aircraft being tested that can best be done during the ground or flight operation of the aircraft.

(2) Tests: aircraft engines

(a) Each engine (except rocket engines for which the manufacturer must establish a sampling technique) shall be subject to an acceptable test run that includes the following:

1 Break-in runs that include a determination of fuel and oil consumption and a determination of power characteristics at rated maximum continuous power or thrust and, if applicable, at rated takeoff power or thrust.

2 At least five hours of operation at rated maximum continuous power or thrust. For engines having a rated takeoff power or thrust higher than rated maximum continuous power or thrust, the five-hour run must include 30 minutes at rated takeoff power or thrust.

(b) The test runs required by paragraph (a) of this section may be made with the engine appropriately mounted and using current types of power and thrust measuring equipment.

(3) Tests: propellers. Each variable pitch propeller shall be given an acceptable functional test to determine if it operates properly throughout the normal range of operation.

Assembly and Test Considerations for Completed Products

The effectiveness of the control exercised throughout the manufacturing cycle to ensure that quality objectives have been met is ultimately determined by the final assembly and test inspections. An acceptable quality control system would, therefore, incorporate final assembly and test procedures to ensure that:

(1) Each completed product is subjected to a final inspection for completeness, adjustments, safety calibration, markings, and placards in accordance with the applicable configuration of the approved design data for the product and model involved. Also, that each product is inspected for freedom from damage, contamination, and for safe operating condition.

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(2) The means provided for leveling an aircraft are accurately installed, and that the empty weight and center of gravity of each completed aircraft are accurately determined. The

holder of a production certificate may submit, for FAA consideration, a proposal based on a reliable statistical plan and evidence of product uniformity, if he desires to utilize an average empty weight and center of gravity, in lieu of weighing each aircraft.

(3) The aircraft equipment list and, when applicable, loading charts and instructions are accurate.

(4) Functional tests of each completed product are conducted to determine whether the operating characteristics meet the approved design provisions. Examples of the type of tests generally found to be acceptable are as follows:

(a) Each completed aircraft would be subjected to a flight test in accordance with flight test procedures and checkoff lists developed from operation characteristics and data which were found to comply with the applicable airworthiness regulations during the type test evaluation program, and approved as a part of the quality control data.

(b) Except as noted in subparagraph 4 below, each completed engine would be subjected to a test run, including:

1 Break-in to determine that engine operating parameters are as specified in the type design data.

2 Internal inspection is necessary to determine that the engine is in condition for safe operation. The degree of such inspection may be based on a statistical sampling plan, evidence of product uniformity, a satisfactory history of previous internal inspections, and service experience.

3 Determination of test instrumentation and power/thrust absorption devices, tolerances and correction to ensure that no production engine can be delivered with less than its type certificated rated power/thrust.

4 Test firing of a sufficient number of rocket engines, selected from production lots in accordance with statistical sampling plans included in the manufacturer's quality control data, which, together with the close control of materials and processes, would ensure that each engine in the lot functions properly and developed its rated thrust for the time specified in the approved type design data.

5 Each completed variable pitch propeller would be functionally tested to determine that it operates freely and smoothly throughout the normal range of operation, with maximum and minimum operating forces alternately applied, according to design and installation requirements.

Airworthiness Certification of Completed Products

(1) Major assemblies and components, comprising a complete aircraft, manufactured under a production certificate may be exported prior to final assembly, inspection, and flight test in accordance with FAR 21.325(b), providing the holder of the production certificate has established FAA-approved assembly and flight test procedures; and the extent of disassembly is the same as an aircraft which has been disassembled for shipment purposes.

(2) Completed products are considered to be submitted for airworthiness certification or approval when an engine or propeller is released for shipment, or in the case of an aircraft, when any one of the following documents as applicable, is completed, dated, signed, and submitted to an FAA representative.

(a) Application for Airworthiness Certificate, FAA Form 8130-6.

(b) Conformity Certificate - Military Aircraft, FAA Form 8130-2.

(c) Application for Export Certificate of Airworthiness, FAA Form 8130-1.

ARAC Working Group ADVISORY CIRCULAR Proposal

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Subject: Handling Standard Parts and Commercial Parts

1. Purpose: This advisory circular provides guidance for a design approval holder to declare parts, included in the type design, which it wishes to define as either Standard Parts or Commercial Parts in accordance with the recently published definitions in Part 1 of the Federal Aviation Regulations. The new definitions are intended to help identify parts that do not require manufacture by an FAA production approval holder. The implementation of these definitions shall not take away the ability for an installer to make a determination of installation eligibility under FAR 43.13 of appropriate parts.

2. Related Federal Aviation Regulations, Advisory Circulars and Reference Material:
   a.) Part 1 Extended Definition of Standard Part
   b.) Part 1 Definition of Commercial Part

3. Discussion: Many parts which are incorporated into the type design of aeronautical products which are of relatively simple design and which in most instances are no more critical to the product airworthiness than AN, MS, etc., nuts and bolts, have for many years required Parts Manufacturer Approval (PMA) for regulatory approval. This has placed a burden on the FAA out of proportion to the parts criticality. Similarly, many parts included in the type design of aeronautical products are commercial off-the-shelf parts such as light bulbs, fire axes, batteries, etc., which have for many years had no formal regulatory basis of approval and for which there has been little or no prospect of the manufacturers of such parts ever making application to the FAA for Parts Manufacturer Approval (PMA).

   In the future the design approval holder will be permitted to declare these parts as either Standard Parts or Commercial Parts in accordance with the definitions for each category released in Part 1 of the Federal Aviation Regulations, and approved by the FAA through the type design approval process. Whether or not the design approval holder has declared parts as standard / commercial, the installer continues to have the ability to install parts that meet the performance standards of Part 43, even if the parts are not produced by a production approval holder.

4. Definitions[1]:
   4.1 Industry Standard Part: a part which meets one of the following criteria

   (a) A part manufactured to a specification prepared by a standards setting organization, which includes the engineering data, the manufacturing process data and uniform identification requirements. The specification must include all information necessary to produce and conform the part. The specification must be published so that any party may manufacture the part. Examples include but are not limited to National Aerospace Standards (NAS), Air Force – Navy Aeronautical Standard (AS), Military Standard (MS).

   (b) A part manufactured to a specification established by a FAA design approval holder that is included in the type design and meets the following criteria:
      (1) The specification contains design, manufacturing, test and acceptance criteria and uniform marking requirements.
      (2) The specification is available to any person so that anyone may manufacture the part.

[1] The final NPRM wording should replace the definitions below, if different. If these definitions change, the rest of this draft should be reviewed for consistency with the new definitions.

(3) The part is not subject to special quality assurance oversight by the PAH.

(c) A part manufactured to a specification that the Administrator finds will result in a part that may be conformed (airworthiness established) solely on the basis of meeting performance criteria and uniform marking requirements.

(d) A part manufactured to a specification for a non-programmable electrical or electronic part produced in conformance with a specification published and maintained by a consensus standards organization, a government agency or a holder of a design approval; or in conformance with the manufacturers internal specifications or standards. The internal specifications or standards must include manufacturing controls, quality and reliability test methods and identification requirements. They may include acceptance test criteria. With the exception of parts manufactured to U.S. Military specifications, design of which are controlled by the Defense Supply Center, Columbus (DSCC), the specifications or standards do not include electrical parameters and data, these are obtained from the suppliers data sheet. The part is used within the manufacturer's published operating and environmental ranges.

4.2 Commercial Part

A detail part or a subcomponent included in the type design that is designated by the design approval holder based on the following criteria:

(1) The part is not necessarily designed for application in commercial aviation and.....

(2) The part is manufactured to a specification or catalog description and marked under the identification scheme of the manufacturer.

5. Procedure: The procedure for a design approval holder to designate and receive regulatory approval for either an industry standard part, 4.1.(b) above or a commercial part 4.2 above, is the same in both cases.

5.1 Step One: The design approval holder prepares two lists, one for standard parts and one for commercial parts. The lists shall include manufacturers name and address of parts included in the type design that it wishes to declare as a commercial part.

5.2 Step Two: The design approval holder submits the two individual and separate lists to the local Aircraft Certification Office (ACO) for approval.

5.3 Step Three: The FAA ACO by comparison with the type design reviews the lists submitted and approves these as appropriate.

5.4 Step Four: The approved lists are published by the design approval holder (e.g., in Instructions for Continued Airworthiness, Illustrated Parts Catalog, listing of manufacturer's standard parts, etc.).

6. Revisions: The design approval holder may make revisions to the standard and commercial parts lists (e.g., adding a new manufacturer) under a system approved by the FAA.

March 21, 2002

Recommendations for Consistent Application of ODAR processes for PAH Shipments

Background

With the proposed NPRM requirement to issue airworthiness approvals for all shipments, AIR-200 had proposed that the Parts and Production ARAC Working Group take an action item to make "recommendations on ODAR personnel qualification requirements who issue these approvals". I have been working on this and have some recommendations to propose for your review and comments.

Proposed changes are to FAA Order 8100.8A "Designee Management Handbook", I confirmed with Mary Hoff (FAA) that all the requirements for the creation and operation of the ODAR are contained in this Order. I also coordinated this with Dale Gordon, Rolls-Royce Corp., who was doing a similar project for AIA.

Summary of Proposed Changes

Current production approval holders (PAHs) already have the responsibility per CFR 14 part 21 to assure parts meet approved design and are airworthy/safe (if it is a PC, PMA or TSO holder the part 21 the wording is a little different for each). The only difference in the new NPRM requirement is that the people who issue the airworthiness approvals under the ODAR must know the FAA requirements for issuance of FAA form 8130-3's. FAA Order 8100.8A is very clear in paragraph 401 (Table II) under Regulatory Appointment Criteria, that "it is the ORGANIZATION that must meet all DAR qualifications for authorized functions identified... The ODAR is responsible for ensuring the individual authorized representatives...COLLECTIVELY meet the overall qualification criteria... not each individual...".

To alleviate the impact on PAH and FAA resources for airworthiness approval functions in the new NRPM requirements, the FAA should shift some responsibilities to the ODAR focal points in the PAHs. Below is a summary of the proposed changes:

- PAH's ODAR focal point could be approved to provide equivalent training to the authorized representatives. The training could be included in the PAH's ODAR Procedure Manual that is approved by the FAA. It would be kept up to date by requiring the ODAR focal point to attend the FAA Standardization Training at least every two years.

- The ODAR focal point could be given the authority to appoint new ODAR authorized representatives for airworthiness approval functions. As they are added to the ODAR Procedure Manual the FAA would do a post review approval.

- The ODAR focal point would have the authority to assign/reassign authorized functions to the ODAR authorized representatives as long as they are authorized

functions already approved for the ODAR. After the functions are assigned the FAA would do a post review approval.

Supporting Paragraphs already contained in FAA Order 8100.8A

Throughout the Order reference is made to the applicant or designee. In the case of an ODAR, the organization is the applicant and the designee.

Paragraph 203. APPOINTING OFFICE MANAGER.

f. Sign or coordinate on all designee appointments or candidacies after the EP decision has been reached.

In the above paragraph the designee in question is the ODAR and any subsequent appointments within the ODAR can be "coordinated". The "EP (Evaluation Panel) decision" again is for the ODAR and subsequent reviews of candidate qualifications are part of the ODAR procedures manual (Reference paragraph 405.a.(4)).

and

Paragraph 902.b. Oversight Considerations Unique to ODAR's. It is the ODAR's responsibility to comply with all provisions of their organizational designation. The ODAR will perform and document self assessments activities to ensure only qualified authorized functions are performed in accordance with the pertinent regulations, related policies, and procedures. The Advisor will provide direct supervision by interfacing with the organization's focal point and monitoring these self assessment activities. The managing office will review and provide written approval of all changes to the ODAR's FAA-approved procedures manual. This shall include any additions or removals of individual authorized representatives who perform authorized function(s). At the appointing/managing office's discretion, changes may be approved before or after implementation by the ODAR.

Specific Changes Proposed for Order 8100.8A

Para. 405. ODAR APPLICATIONS. Add new para. 405.a.(6) to say:

(6) Defines the training requirements for individual authorized representatives.

Para. 405.b. ODAR Focal Point. Revise paragraph to say:

The application for an ODAR must be signed by the proposed focal point. The proposed focal point is a management official within the applicant's quality organization who will have sufficient authority to effect change within the ODAR. The ODAR focal point will

be responsible for management and oversight of the ODAR, including; authorization of representatives, assignment / reassignment of representatives and equivalent standardization training as permitted by the ODAR manual. The management representative will serve as the FAA focal point for ODAR activities. Any changes in an ODAR focal point shall be reported to the FAA Managing Office.

Para. 802. SEMINAR ATTENDANCE. Add the following to the end of 802.b. NOTE to say:

Authorized ODAR representatives, that only perform airworthiness approvals at a PAH (Class II/III product airworthiness approvals) can obtain equivalent training through the ODAR. The PAH's ODAR can provide equivalent training to authorized representatives. The training program would be included in the PAH's ODAR Procedures Manual that is approved by the FAA. The training program would be kept up to date by requiring the ODAR focal point to attend the FAA Standardization Training at least every two years and update the program accordingly.

Para. 902. MANUFACTURING DMIR/DAR/ODAR OVERSIGHT (SUPERVISION, MONITORING, AND TRACKING).

Modify paragraph 902.a.(1)(c) to say:

(c) Verify that the designee's attendance at the appropriate standardization seminar is in accordance with this order. Verify attendance at the appropriate standardization seminar or equivalent training by each representative performing an authorized function(s) under an organizational designation in accordance with this order.

Add a NOTE to paragraph. 902.b. to say:

NOTE: For airworthiness approval functions (Class II/III product airworthiness approvals) at a PAH, the ODAR focal point can provide equivalent standardization training, appoint new authorized representatives, and assign/reassign these functions to authorized representatives as provided in the ODAR Procedures Manual. The FAA managing office would review and approve the ODAR Procedure Manual changes at its next opportunity.

REPLACEMENT AND MODIFICATION PART DESIGN APPROVAL PROCEDURES

February 2001
(ARAC Draft)

A-W(IR)-3; A-X(CD)-3; AIR-110
A-FAC-0(ALL); AEU-100;
A-FAC-3(ALL); FDR-2;
AMA-220 (25 copies);
FS-600 (3 copies)

ARAC FAR 21/45/1
P. Gallimore, Chairman
ORIGINAL DRAFT 4-4-00

FOREWORD

This document developed through the ARAC (Aviation Rulemaking Advisory Committee) contains guidelines for both FAA personnel and applicants for acquiring and maintaining Parts Design Approval (PDA) for replacement and modification parts. A PDA may be obtained for a part replacing or modifying all previously approved part designs. The major change is the uniform requirement for all parts to have a design approval and a production approval (PDA and PPA, respectively) to the same design and production standards as applicable to TC and PC holder. Standard parts and commercial parts are specifically excluded from requiring FAA parts design and production approvals. They are defined herein. Owner- operator parts also are excluded, but new Owner Produced(OP) Parts identification requirements are described.

A separate document (AC 21-1C) will describe the quality system changes required to go from a current PMA Fabrication Inspection System (FIS) to the new Parts Production Approval (PPA) Part 21 Subpart G production approval requirements. There is a two-year phase-in period for these changes to be implemented. At the time a PMA holder receives its PPA, the design approvals of all former PMA's held will continue to be approved designs. Parts previously approved by the FAA under a PMA will remain approved.

This Order is applicable to all FAA engineering and manufacturing personnel, and to all parts design and production approvals.

James C. Jones
Manager, Aircraft Engineering Division
Aircraft Certification Service

1. **PURPOSE.** This Order [or Advisory Circular] prescribes the responsibilities and procedures for Federal Aviation Administration (FAA) aircraft certification personnel responsible for the approval process required by the Federal Aviation Regulations (FAR) for design approval of replacement or modification parts for installation on a type certificated product. It also serves as an advisory to all applicants. Although this document represents comprehensive instructions and guidance, compliance with all applicable elements of FARs is required.

2. **DISTRIBUTION.** This Order is distributed to the Washington Headquarters branch levels of the Aircraft Certification Service, to the branch level of the Regional Aircraft Certification Directorates, to all Aircraft Certification Offices (ACO), the Brussels Aircraft Certification Staff, to all Manufacturing Inspection District Offices (MIDO), to all Manufacturing Inspection Satellite Offices (MISO), and to all Designated Engineering Representatives (DER). This Order is available to all applicants, and it is also available on the Internet.

3. CANCELLATION. FAA Order 8110.42A, Parts Manufacturer Approval Procedures, dated March 31, 1999, is cancelled two years after the date of this order. **[NOTE: date to be revisited by the FAA depending upon the date of release of this Order versus the date of the Final Rule]**

4. **EFFECTIVE CHANGES.**

a. **Parts Design Approvals (PDAs).** All approvals issued or applications submitted before the date of this Order will remain in effect. Design applications submitted after six months from this date must be processed in accordance with this Order.

b. **Part Production Approvals (PPAs).** All production approvals issued or applications submitted before the date of this Order will remain in effect. PPA applications submitted after this date shall be processed in accordance with AC 21-1C [or Order – we must be consistent with this document and the PPA document]. This phase into the Subpart G System results in a single standard quality system for all product and part manufacturers.

c. **Identification of Parts.** The new identification requirements are effective as part of new design and production approval. The marking changes are considered minor changes. Critical components must be identified per 45.14, including a serial number. Part numbers obliterated by assembly need not be re-identified. TSO part identification requirements do not change.

5. **GENERAL.** This Order describes the procedures and guidance for FAA and applicant personnel to follow when issuing a Parts Design Approval (PDA) in accordance with Code of Federal Regulations Title 14 (14 CFR) part 21 Subpart K . New guidance is provided on making compliance findings by what was formerly called "identicality" and by "test and computations." While the term "identical design" is no longer a specific regulation, this Order recognizes the

approach of utilizing data of a previously approved design (PAD) either wholly or in part through written authorization from the design approval holder, tests and computations, or other methods as described herein.

6. **INFORMATION CURRENCY.** Any deficiencies found, clarifications needed, or improvements to be suggested regarding the content of this order should be forwarded to the Aircraft Certification Service, Automated Systems Branch, AIR-520, Attention: Directives Management Officer, for consideration. Your assistance is welcome. FAA Form 1320-19, Directive Feedback Information, is located on the last page of this order for your convenience. If an interpretation is urgently needed, you may contact the Aircraft Engineering Division, Certification and Procedures Branch (AIR-110) for guidance, however, you should use the FAA Form 1320-19 as a follow-up to a verbal conversation.

7. **DEFINITIONS AND TERMS.** For the purpose of this order the following definitions and terms apply:

a. **Aircraft Certification Office (ACO)** is the field element of the FAA Aircraft Certification Service with geographic responsibility for making a finding that the part design complies with applicable airworthiness standards. The ACO administers and secures compliance with agency regulations, programs, standards, and procedures governing the design approval of replacement and modification parts. The location, addresses, and geographic areas of responsibility of the individual ACO are in Appendix 1, List of FAA Aircraft Certification/Field Offices.

b. **Certificating ACO** is the ACO that has issued and has oversight of the original design approval for the product/appliance on which the PDA applicant's part is eligible for installation.

c. **Commercial part is defined in FAR 1.**

d. **Critical** is a term applicable to parts, appliances, characteristics, processes, maintenance procedures, or inspections when if failed, omitted, or non-conforming, may cause significantly degraded airworthiness of the aircraft during takeoff, flight, or landing. **[NOTE TO FAA: Should this be changed to "priority parts"?]**

e. **Design** consists of all drawings and specifications, which may be summarized on a master drawing list. These are necessary to show the configuration of the part and all information on dimensions, tolerances, materials, processes, and procedures necessary to define all characteristics of a part, as well as the Airworthiness Limitations Section of the Instructions for Continued Airworthiness (ICA).

f. **Eligibility** identifies the type certificated products on which a part designed under Parts Design Approval (PDA) may be installed.

g. Life-limited Part is any part which has an established replacement time, inspection interval, or related procedure specified in the Airworthiness Limitations section under 14 CFR part 21 §§ 21.50, 23.1529, 25.1529, 27.1529, 29.1529, 31.82, 33.4, and 35.4 or mandatory replacement and/or inspections noted or referenced on the product Type Certificate Data Sheet (TCDS), for products certified before airworthiness limitations were added to 14 CFR. Mandatory replacement and/or inspections would also be noted or referenced on a letter of Technical Standard Order approval (PDA and PPA required).

h. Life Management Program is a FAA approved program established by the applicant to assure the continued airworthiness of a life-limited part.

i. Manufacturing Inspection District Office (MIDO) is the field element of the FAA Aircraft Certification Service with responsibility for management of production approvals in the geographic area in which the applicant's fabrication inspection system (or later, Production System) is located. In some areas, a Manufacturing Inspection Satellite Office (MISO) will perform these functions. The location, addresses, and geographic areas of responsibility of the individual MIDO/MISO are in Appendix 2, List of FAA Manufacturing Inspection District/Satellite Offices.

j. Parts Design Approval (PDA). The FAA's approval of the design of a part for which application was made as a replacement or modification part.

k. Parts Production Approval (PPA). The FAA's approval of a documented quality system demonstrated as capable of producing conforming parts.

l. Production Limitation Record (PLR). A FAA document that lists products or parts that the production approval holder is authorized to manufacture under the terms of the production approval.

m. Product is an aircraft, aircraft engine, or propeller and type-certificated appliances(part 21 § 21.1(b)).

n. Standard Part is defined in FAR 1.

8. APPLICABILITY.

a. General. This document provides information to obtain part design approval (PDA) for replacement or modification parts.

b. Falsification of Applications, Reports or Records. No person shall make or cause to be made any fraudulent or intentionally false statement or material omission of fact.

c. Denial of Application. The administrator may deny an application for design approval if any of the conditions in FAR 21.7 exist.

9. PARTS DESIGN APPROVAL. The ACO administers and secures compliance with agency regulations, programs, standards, and procedures and issues parts design approvals. The MIDO/MISO ensures conformity to design requirements. Approval of an application for PDA and PPA requires an approval of the design by the ACO and a quality system approval by the MIDO/MISO (see process flow chart in Appendix 3).

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a. Airworthiness. The applicant for PDA must show that the design meets the applicable airworthiness standards. There are two basic ways that an applicant may show compliance:

(1) Previously Approved Design. The applicant shows that the design of the part is the same as a previously approved design through a written authorization from the design approval holder or as provided in paragraph 10.a.(3)(b).

(2) Tests and computations. The applicant shows through tests and computations, using a comparative or general analysis, as necessary based on the criticality and complexity of the part, to show that the design of the part meets the airworthiness requirements applicable to the product on which the part is installed.

b. Special Considerations: Older Products. In evaluating applications for design approval for parts on older TC products, FAA personnel should consider potential problems facing the applicant. For example, type design information may be difficult to obtain, the product may no longer be in production, or the TC holder may no longer exist or may no longer be producing parts. In all such cases, the applicant must still submit sufficient information to support a determination that the replacement or modification part is equal to or better than the original part. Accordingly, FAA engineering personnel will need to exercise sound and reasonable judgment in considering means of demonstrating compliance.

10. APPLICANT RESPONSIBILITIES.

a. PDA Application. The applicant must submit a letter of application (see Appendix 4, Sample FAA-PDA Letters of Application) to the ACO in the geographical area in which the design organization of the applicant is located. The application should include the following information:

(1) Applicant identification. The name and address of the applicant, and

(2) Part identification. The identity of the part for which PDA application is being made, including:

(a) Product identification. The previously approved product identified by make, model, series, and if appropriate, serial number, on which the part is to be installed.

(b) **Part replaced identification.** The part number that the proposed part would replace.

(c) **PLR.** Include a draft PLR as shown in appendix.

(3) **Method.** A brief description of the method by which design approval will be sought:

(a) **Same design with authorization.** The applicant shows that the design of the part is the same as a previously approved design through a written authorization from the design approval holder of the previously approved design. The applicant should submit an appropriate document from the design approval holder authorizing use of the submitted data package. The evidence of a written authorization is used by the applicant to show that the data submitted is FAA approved and therefore identical. For FAA purposes, the written authorization, in whatever form it takes (such as an "assist letter"), need only authorize the applicant to use the design data specified (see appendix 5, Sample Design Approval Holder's Assist Letter).

(b) **Same design without authorization.** The applicant may show that the, design is the same as a previously approved design. This method may, under appropriate circumstances, be utilized for showing compliance. In these types of parts, a showing of identical design may not in-and-of-itself be sufficient to assure that parts will meet the airworthiness requirements. The applicant can be issued a PDA based solely on a design comparison if the applicant can substantiate that the nature of the part, taking into account its criticality and complexity, does not warrant any further showing. As stated, this process would be a viable method for showing the design meets the airworthiness requirements as long as the applicant and the FAA exercise the proper considerations. The applicant would substantiate this method by providing the FAA with necessary data based on the complexity and criticality of the part. This method would also be used in conjunction with other methods to show the design meets the airworthiness requirements. For instance, it could be combined with test reports and computation methods where testing may or may not be required depending on the criticality and complexity of the part. Those additional tests and analyses found necessary to make a finding of "same design without authorization" do not change the basis of PDA approval to "Test and Computation". If the results of these additional tests and analyses are such that the ACO finds that the produced PDA part is not the same as the previously approved part, the ACO must reject the PDA application.

NOTE: FOR CRITICAL PARTS TO BE APPROVED IN THIS MANNER, NO DEVIATION IN PART DESIGN OR MANUFACTURING PROCESSES IS ALLOWED. HENCE, UNDER THE PPA FOR THESE PARTS, THE PLR SHALL SPECIFY THAT NO DEVIATION IN PART DESIGN OR MANUFACTURING PROCESS IS ALLOWED.

Aircraft that no longer have an active design approval holder from which data can be obtained to support the design of parts need special consideration in order to continue flying. These aircraft are primarily and almost exclusively involved with personal or sport flying and are not being used for carriage of passengers for hire. In these instances where data is not available or where

the needed part is not critical to safety, more consideration should be given to the use of this method, or a "form, fit, and function" analysis.

(c) Test and computations. The applicant shows through tests and computations that the design of the part meets the airworthiness requirements applicable to the product on which the part is installed. This method requires all design, materials, processes, test specifications, system compatibility, and interchangeability are supported by the appropriate substantiation data and tests, as necessary depending on the complexity and criticality of the design, for FAA review and approval. The applicant must assure that no detrimental interference with mating or adjacent hardware occurs and that the part performs its intended function.

COMPARATIVE ANALYSIS: The applicant may show by comparative analysis and general analysis that the part is equal to or better in functional design than the design of the type certificated or PDA part that would be replaced. The applicant would thoroughly analyze the type-certificated part and compare it with the proposed PDA part, report all differences and provide sound technical justification for these differences. If testing is required, a new (zero time since new) FAA approved part tested under the same procedures and conditions as the applicant's part shall be used as a test standard.

GENERAL ANALYSIS: The applicant may demonstrate by general analysis that the functional design of the part otherwise meets the requirements of all applicable airworthiness standards. This analysis should discuss how the part meets applicable Federal Aviation Regulations and address material composition and condition, fabrication, configuration, and interface with other parts. Functional testing as necessary would be related to the criticality and complexity of the part.

b. Data package. Regardless of the basis upon which PDA is sought, the application must include information that the part meets the requirements of Part 21 and the airworthiness requirements of the Federal Aviation Regulations (or their predecessors) applicable to the product on which the part is to be installed. The complexity of the data package necessary to meet these requirements will vary depending upon the critical nature of the part as it relates to the product on which it is proposed to be installed. The information required may extend to the manufacturing controls, fabrication processes, assembly techniques, and the performance, endurance, and test requirements if they are necessary to establish the airworthiness of the part in accordance with applicable regulations. The data package may include, but is not necessarily limited to, the following:

(1) Design. One copy of the applicant's drawings and specifications necessary to show the configuration of the part. Drawings and specifications should address dimensions and tolerances, materials, and processes necessary to define the structural strength and all design characteristics of the part. The required information for some parts (e.g., those determined to be critical and/or life-limited) may include routing sheets, tooling requirements, process sheets, material handling/storage, and/or inspection requirements as deemed necessary by the FAA.

(2) Inspection and test procedures. For parts determined to be critical and/or life-limited, the FAA may require demonstration of the manufacturing process, inspection and test procedures (including process controls, and finished product performance) in order to obtain design approval. This data should include, but not be limited to, all elements of the manufacturing cycle (e.g., raw material purchase, material chemistry and grain, structure evaluation, fabrication, melt forging, machining, surface treatments, other material properties, required inspections, etc.) and any other data required to show that the applicant's part meets the approved design. If the application is based upon test and computation both design and manufacturing substantiation should be provided if necessary, considering the complexity of the part. If the application is based upon being the same as a previously approved design, necessary manufacturing procedures should be submitted to demonstrate the above.

(3) Test results. For parts determined to be critical and/or life-limited, the FAA may require the applicant to perform inspections, tests, and provide the test results necessary to show the airworthiness of parts produced are in conformity with the proposed design in order to obtain design approval. Where premature component failure would have affected the result of type certification tests addressing overall product safety, durability and performance, the part must be subjected to necessary testing to demonstrate it meets the airworthiness requirements regarding safety, durability and performance.

If the application is based upon a previously approved design, the applicant should submit test results necessary to demonstrate that the airworthiness of the part is not altered by the manufacturing methods and processes as performed by the applicant.

(4) Airworthiness limitations. For life-limited parts identified in Type Certificate Data Sheets or airworthiness limitations section, the method necessary to accurately assess fatigue life must be established and will include the appropriate elements. This shall be performed for the replacement or modification part and/or any life limited mating parts. For example, if the PDA part is a turbine blade, an assessment must be made on the life impact of the life limited disk on which it is installed.

NOTE: FOR NON-LIFE-LIMITED CRITICAL PARTS, IT IS THE RESPONSIBILITY OF THE ACO TO ASCERTAIN WHETHER OR NOT THE APPROVED PART'S DESIGN WAS LIFE-ASSESSED BY THE TYPE CERTIFICATE HOLDER. IF THE APPROVED PARTS DESIGN WAS LIFE-ASSESSED, THEN EVALUATION OF THE LIFE OF THE PDA PART IS REQUIRED. THE COMPLAINCE PLAN FOR A LIFE ASSESSED CRITICAL PDA PART MUST INCLUDE A PROPOSED FATIGUE LIFING METHODOLOGY AND TEST VALIDATION PLAN TO BE USED FOR THE ESTABLISHMENT OR VERIFICATION OF THE INITIAL PART LIFE AND IN SUPPORT OF A CONTINUED AIRWORTHINESS LIFE MANAGEMENT PROGRAM.

(5) Emissions and noise. If the design of the replacement or modification part will change the emissions or noise profile of the aircraft, those changes must be addressed in accordance with 14 CFR parts 34 and 36.

(6) Life Management Program. If the replacement or modification part has a life limit, the applicant must also provide for FAA approval an appropriate Life Management Program. The program should provide for detailed records of all aspects of the manufacturing cycle maintained for the entire life of the part and should provide details of how to segregate an affected population, if necessary. In-service part usage must be continually monitored and design assumptions continually reviewed against the in-service experience. If a failure condition is identified, the applicant must have procedures to identify the problem, develop the corrective action(s), and implement action(s) into the field in an appropriate time frame.

(7) Part marking. Part marking information necessary to insure that compliance with 14 CFR part 45 (including critical components marked in accordance with part 45 § 45.14) will not interfere with airworthiness considerations.

(8) Installation eligibility. Detailed information sufficient to demonstrate understanding of products or parts on which the replacement or modification part may be installed (make, model, series, and if appropriate serial number), how it relates to the next higher assembly of which it is a part, and the consequences for the next higher assembly and the product if the part should fail.

(9) ADs and SDRs. The applicant should identify all airworthiness directives or unresolved service difficulties involving the part being replaced.

(10) Installation eligibility or Instructions for Continued Airworthiness / Maintenance Instructions. The applicant must furnish the installation eligibility of the replacement or modification part. The applicant must also furnish information sufficient for the FAA to determine that the Instructions for Continued Airworthiness (IFCA)/Maintenance Instructions for the original part will continue to be valid for the product with the PDA part installed. If the original IFCA/Maintenance Instructions are not valid with the PDA part installed, the applicant must furnish supplementary IFCA/Maintenance Instructions. The applicant's IFCA/Maintenance Instructions will be reviewed and approved (if appropriate) by the ACO and Flight Standards Aircraft Evaluation Group.

c. Special Requirements - Test and Computation Applications. Applications submitted on the basis of test and computation should specifically address the following:

(1) Airworthiness. Applications based upon test and computation must show that the design of the part meets the airworthiness requirements applicable to the product on which the part is installed. Airworthiness standards are found in the following Federal Aviation Regulations (14 CFR, Chapter I) or their predecessors:

(a) Part 23, Airworthiness Standards: Normal, Utility, Acrobatic, and Commuter Category Airplanes.

(b) Part 25, Airworthiness Standards: Transport Category Airplanes.

(c) Part 27, Airworthiness Standards: Normal Category Rotorcraft.

(d) **Part 29,** Airworthiness Standards: Transport Category Rotorcraft.

(e) **Part 31,** Airworthiness Standards: Manned Free Balloons.

(f) **Part 33,** Airworthiness Standards: Aircraft Engines.

(g) **Part 34,** Fuel Venting and Exhaust Emission Requirements for Turbine Engine Powered Airplanes.

(h) **Part 35,** Airworthiness Standards: Propellers.

(i) **Part 36,** Noise Standards: Aircraft Type and Airworthiness Certification.

(2) **Substantiation.** To show compliance with the applicable airworthiness requirements under test and computation, the applicant must provide either a comparative and/or a general analysis. If appropriate and necessary, the analysis should be supported by an FAA approved test plan and test results. The analysis must be supported by the engineering assessment of the consequences to the next higher assembly and the product, should the part fail to perform its intended function.

(a) **Analysis.** There are two acceptable methods of analysis: comparative and general.

1 **Comparative analysis.** The applicant may demonstrate by comparative analysis that the part is equal to or better in functional design than the approved design of the part that would be replaced. The applicant shall thoroughly analyze the approved part and compare it with the proposed PDA part, report any differences and provide sound technical justification for these differences.

2 **General analysis.** The applicant may demonstrate by general analysis that the functional design of the part meets the requirements of all applicable airworthiness requirements. This analysis should discuss how the part meets applicable Federal Aviation Regulations of the previously approved design and address material composition and condition, fabrication, configuration, and interface with other parts. For example, a revised TSO specification may be "grandfathered."

(b) **Testing.** Functional testing may or may not be required of the applicant's part. Testing should be related to the criticality and complexity of the part. The component testing and/or ground/flight testing, if required, shall be designed to test the performance and durability of the part to the extent required to show airworthiness. The applicant should identify the number of test units, unit identification, test conditions and duration, test criteria, test safety control, and control of test procedures. To accomplish this, the applicant shall submit a test plan, including a request for part conformity, for FAA approval. Following FAA approval and part conformity, the applicant shall conduct the test(s) and post

test inspections, both of which may be witnessed by a representative of the FAA. Following the post test inspection, the applicant shall submit a test report. This report shall include an analytical evaluation of the test results and post-test inspection results and a comparison of these results to the test standard. The following should be used as a test standard against which the adequacy of the PDA part will be measured:

1 **Approved part.** A new (zero time since new) previously approved design part tested under the same procedures and conditions as the PDA applicant's part.

2 **Verification.** Verification that the part meets applicable airworthiness requirements.

3 **Other.** Other tests deemed acceptable by the Administrator.

d. Part Marking Requirements. Parts must be marked in accordance with FAR 45. The identifying marks should be included on the design data and reviewed as part of the FAA engineering approval of the design, in part, to establish that the location and process of identification does not degrade airworthiness compliance. Parts with a PMA design approval may continue to be marked in accordance with the approved design.

(1) Part Numbering Requirements. The applicant's part should be numbered such that it is distinguishable from the specific part number it replaces. The FAA-PDA document will show the original approved part number with which the applicant's part is interchangeable.

(a) Supplier. For a supplier to a PAH in which the supplier's part number is used by the PAH, the PDA holder may use the same part number as the design approval holder, provided the PDA holder also meets the requirements of part 45.

(b) Written authorization. Part Design Approval Obtained Through Written Authorization. When the PDA is issued by showing evidence of a written authorization, the part number may be identical to that of the previously approved design, provided the applicant also meets the requirements of part 45.

e. Part Eligibility. Part eligibility will be listed by the PDA holder in a document or catalog readily available to the installer. If there are no special instructions for continued airworthiness (IFCA) for the PDA parts compared to the original parts, this listing will satisfy the requirements of FAR 21.303(e).

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f. Post PDA Activities.

(1) Reporting of Failures, Malfunctions, and Defects under part 21 § 21.3. The PDA holder should establish a procedure to report to the FAA any failure, malfunction, or defect of a part that could result in, or has resulted in, one of the occurrences listed in FAR 21.3.

(2) **Additional Part Installation Eligibility Approvals.** A PDA holder may apply for additional installation approvals for the part. The applicant should submit the information required by paragraph 10.b.(8) of this order, to the extent that it applies, to obtain approval of the additional installation(s). If the FAA finds that the applicable IFCA/Maintenance Instructions for the product (or PDA part) is valid with the replacement or modification part installed, the part will be approved as eligible for installation on that product or products.

(3) **Design Changes.**

(a) **Minor/Major PDA.** The PDA holder shall submit minor changes to existing approvals in accordance with procedures agreed to by the FAA. Major changes must be substantiated and approved prior to implementation in the same manner as that for the original PDA.

(b) **Major/TSO.** If the installation of a replacement or modification part would constitute a major design change to a TSO article, then the applicant must obtain a new TSODA.

(c) **Product relationships.** To introduce a design change, the PDA holder should have an understanding of the relationship of that change to the type-certificated product.

11. **ACO RESPONSIBILITIES.** The cognizant ACO has the following responsibilities with respect to applications for PDA.

a. **The ACO** in the geographical area in which the applicant is located should accept the application for PDA (sample provided in Appendix 4, Sample Letters of Application).

b. **The ACO** should review the applicant's engineering design to determine whether the design meets applicable airworthiness requirements. In performing this review, the ACO should:

(1) **Data.** Consider all substantiating data submitted by the applicant to show compliance with applicable airworthiness requirements.

(2) **Airworthiness.** Determine whether the application for PDA establishes that the part meets the airworthiness requirements applicable to the type certificated product on which the part is to be installed, and verify the eligibility for installation on the type certificated product. The ACO should consider the following in evaluating each potential basis for design approval.

(a) **General considerations**. Applicants may combine the method of showing compliance. However, irrespective of the method by which an applicant chooses to

show compliance, prior to issuance of design approval, each application must be carefully reviewed in coordination with MIDO as appropriate and necessary (i.e., issue requests for conformity inspections) to determine whether the applicant can ensure:

1 **Airworthiness.** Compliance with the applicable airworthiness requirements.

2 **Materials.** That materials conform to the specifications in the design.

3 **Design.** That the part conforms to the drawings in the design.

4 **Processes.** That the applicant has demonstrated that the manufacturing processes, construction, and assembly conform to those specified in the applicant's design.

5 **Reporting.** The applicant has established reporting procedures under part 21 § 21.3, for the part and the product upon which the part is installed.

(b) Eligibility. Verification of installation eligibility – lacking documentation from the holder of the previously approved design, the ACO should consider all evidence submitted by the applicant and may check other documents including the type design Master Drawing List in making its finding. The Manufacturers' Illustrated Parts Catalog (IPC), while it does provide information that pertains directly to installation eligibility, is usually not FAA-approved. The IPCs should be used in conjunction with other data (examples include: purchase orders from the PAH, service bulletins, maintenance manuals, technical publications index, and/or master drawing list). In certain instances, where safety is not impacted by the installation (such as interior trim pieces), the IPC may be used as the sole means of verifying installation eligibility. When the IPCs are used as the sole means of verification the authenticity of the IPCs should be verified. The IPC shall not be used to make any engineering finding leading to approval of the applicant's design data, nor to determine part conformity.

(c) Service history. Service history considerations. Depending on the criticality of the part, the ACO may perform an in-depth review of the service history of the part. For all parts the ACO will verify that the part is not the subject of an airworthiness directive (AD), other continued airworthiness problem(s), or subject to an incident or accident investigation where the part may be suspect. If the part is subject to one of the above, and the design is identical or substantially identical in a material way to the problem, then the following guidelines should be used:

1 **Remove from service.** If there is an AD that removes the previously approved part from service, immediately or in the future, the PDA application shall be examined for relevance.

2 **Under consideration.** If the FAA is currently developing or considering development of an AD to remove the previously approved part from service, the ACO should examine the PDA application for relevance.

3 **In investigation.** If the FAA is investigating an incident or accident where the previously approved part may be suspect, the ACO should delay the processing of the PDA application until the part is cleared.

4 **Inspection.** If an AD calls for repetitive inspections but prescribes no terminating corrective action (e.g., modification or replacement of the part) and if the repetitive inspections are intended to catch failures that may occur before the part reaches the published service life, the FAA should examine the PDA application for relevance.

5 **New design.** For a part that is not identical or substantially identical to the previously approved part, the ACO should determine whether installation of the applicant's part would create an unsafe condition.

6 **Service Bulletin removal.** The fact that the design approval holder issues a Service Bulletin to remove a part from service does not in and of itself exclude issuance of a PDA, however its relevance should be fully examined.

7 **Current service difficulties.** If the part is experiencing service difficulties and the FAA is ACTIVELY pursuing corrective action with the design approval holder, the application for PDA should be examined for relevance, and if appropriate, delayed pending outcome of the corrective action.

(d) Life-limited parts. Irrespective of the method under which an applicant seeks a PDA, a life-limited part must be substantiated in accordance with paragraph 10c(2). The substantiation must establish the life limits and airworthiness of that part. The required substantiating data must include tests on components produced by the applicant.

(e) Special considerations - Evidence of a written agreement. The evidence of written agreement from a design approval holder must include written permission for the applicant to use the design data to apply for PDA. A "PDA assist letter" (see appendix 5, Sample design approval Holder's Assist Letter) or similar evidence authorized by the design approval holder is sufficient for showing evidence of a written agreement. The applicant must meet all the requirements of part 21. The "PDA assist letter" should include the following information, as appropriate:

1 **Identification.** Product model, name, and design approval identification.

2 **Authorization.** A statement that the PDA applicant is authorized to use the design data, identified by part name and drawing number and revision level

3 **Part numbers.** Information on the authority of the PDA applicant to use the design approval holder's part number and other part marking information as appropriate including authority to use a new part number.

4 **Life limits.** Information that establishes the life limits and/or the airworthiness limitations of the part and the next higher assembly, as appropriate.

5 **Eligibility.** Information on the parts eligibility for installation (product make, series, model and if appropriate the serial number).

6 **Design changes.** A statement as to whether design changes to the part and disposition of non-conforming parts will be controlled through the original design holder's quality assurance process, and how design change information will be related to the applicant and subsequently to the FAA.

(f) Special considerations for design approval based on applicant's design being the same as a previously approved design.

1 **Approval requirements.** Engineering approval of the design can be accomplished when the applicant shows and the FAA finds that the design of the part for which PDA is requested has the same dimensions, tolerances, materials, processes, and specifications to the design of the part covered under a previously approved design.

2 **Critical parts.** For critical and life-limited parts, coordination with the certificating ACO is required.

3 **Exceptions.** Some part designs may contain features, such as color, that have nothing to do with form, fit, or function or being airworthy. It may not be necessary that these features be the same as the previously approved part's features.

4 **Processes.** Many parts rely on specific manufacturing processes to provide the necessary material properties. If detailed knowledge of these processes is not available to the applicant for incorporation into the applicant's design, any request for approval by showing that the PDA part meets the previously approved design will require substantiation of the applicant's part durability and strength in the operating environment.

5 **Drawing Notes.** The ACO must establish that the applicant's data provides the ability to produce conforming parts, before issuing engineering approval. The ACO should pay particular attention when the design approval holder's drawings or specifications used to make a finding based on previously approved designs have notes stating:

(aa) "Parts supplied to this drawing shall be in strict accordance with samples (first articles) approved by *(name of applicant)* engineering department unless prior written approval is given to subsequent change."

(bb) "Source approval is required for raw stock through total fabrication or vendor substantiation required."

(cc) "This drawing represents a critical item and must successfully complete substantiation tests and be approved by engineering." or

(dd) Other similar statements implying special source selection criteria.

NOTE: The ACO will evaluate each applicant's capabilities to produce the part on a case-by-case basis. If the applicant is unable to provide this information, the test and computation method should be used.

6 **Rejection.** When the design data submitted (including the manufacturing processes) does not show that the PDA part is the same as the previously approved design, the application should be returned to the applicant with a notification that it does not show the applicant's part to meet the requirements under this section (see appendix 9, Sample FAA Parts Design Approval Rejection Letter).

7 **Minor design change authority and Material Review Board authority.** Minor design change (and MRB authority in conjunction with a PPA) may be exercised under PDA granted under this section when the applicant submits a license agreement or other evidence that he has been granted such authority by the design approval holder, or by written authorization from the FAA for specific non-critical parts.

(g) Special considerations--Test and Computation for new designs.

8 **Critical parts.** For critical and life limited parts, program coordination with the certificating ACO is required.

2 **Review.** The ACO shall carefully review the showing of compliance through the test and computation method, in coordination with the applicant and, as appropriate, the responsible MIDO/MISO/CMO, to assure adequate substantiation. The responsible engineer in the ACO shall evaluate and approve the test plan , if one is necessary, and if appropriate consult with the certificating ACO, to determine the adequacy of the plan considering the criticality of the part.

(h) Instructions for Continued Airworthiness (IFCA)/Maintenance Instructions. If the applicant is proposing to utilize the IFCA/Maintenance Instructions of the previously approved part, the ACO should determine that the original IFCA/Maintenance Instructions are valid with the PDA part installed. The ACO must also make a determination that the PDA applicant has a procedure to review later revisions to those IFCA's to determine whether they will continue to be valid for the product with the PPA part installed. If the applicant is providing supplemental IFCA / Maintenance Instructions it should be reviewed by the ACO and if necessary coordinated with the appropriate Aircraft Evaluation Group (AEG) of Flight Standards Service.

(i) **Data package.** Evaluating the data package. All applications should include the detailed design criteria including: drawings, technical data necessary to establish structural strength, part marking information, and process specifications necessary to define the configuration, and other data necessary to establish the pertinent characteristics of the part. The applicant's detail drawings must be identified as their own. In evaluating any data package, consideration should be given the following areas:

1 **Processes.** Manufacturing and Process Specifications. Manufacturing procedures and process specifications may affect the airworthiness of the part. If the applicant's detail drawings reference the previously approved design holder's process specifications, those specifications must be submitted. As the data package is reviewed, coordination with the certificating ACO or MIDO may be necessary to determine what effect these specifications may have on the airworthiness of the design. **For critical and life-limited parts, coordination with the certificating ACO is required.**

2 **Source Control Drawings.** Source control drawings must be carefully evaluated to determine whether the applicant has appropriate control over the configuration of the part. The applicant must submit all applicable detail drawings and specifications for evaluation of the sources listed on source control drawings.

3 **Conformity.** Coordinate requests for conformity inspections with the appropriate MIDO/MISO/CMO to ensure that the manufacturing process produces replacement and modification parts according to the approved design.

(j) **Applicant Resources.** It is the responsibility of the applicant to secure the necessary technical expertise to sufficiently support the design, manufacturing, and continued airworthiness efforts required for critical PDA parts. It is essential that these resources are validated.

d. **Design approval.** When the ACO has found that the applicant has shown compliance with the applicable airworthiness requirements, the ACO should do the following:

(1) Retain the submitted application and approval for its files.

(2) Send the applicant the Part Design Approval document.

e. **Non-Compliance.** If the ACO cannot make a finding of compliance they should send the applicant a rejection letter (see appendix 9, Sample FAA Design Approval Rejection Letter) and return the applicant's data package in its entirety.